



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/825,752 | 04/16/2004 | David Hung | 12.023011-CIP | 8506 |

38732 7590 08/29/2006

CYTYC CORPORATION
250 CAMPUS DRIVE
MARLBOROUGH, MA 01752

| |
|----------|
| EXAMINER |
|----------|

BROWN, MICHAEL A

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3764

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 10/825,752 | Applicant(s) HUNG ET AL. | |
| | Examiner Michael Brown | Art Unit 3764 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of U.S. Patent No. 6,391,026. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the present invention only positively recites a method of treating a breast comprising applying vibration to the duct (where to the duct can be internal or external to the breast). Claim 26 of Hung recites the same method comprising treating a breast by vibrational energy. Although the vibrational energy of Hung is used to activate the agent in the duct, the result is still an application of ultrasound to the duct. The vibrational energy of the Hung patent is also used to increase the amount of retrievable cells via activation of the agent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Endo '327.

Claims 1 and 3 of the present invention only positively recite a method of treating a breast comprising applying vibration to the duct (where “to the duct” can be external to the breast). The “increasing a retrievable cell amount” by “inducing cell sloughing” is an inherent result of vibration applied to the breast. According to the specification of the present invention, there doesn’t appear to be any specific vibrational frequency or specific application method needed to achieve the desired result. In fact, the specification recites on page 12, lines 19-19, the method can also comprise applying vibration or other motion or movement internally or externally to the breast by device, not limited to, ultrasound and other sonic devices.

Since claim 1 can be interpreted very broadly, the Endo vibration device when applied to the breast (col. 2, lines 67-68) would inherently provide the desired result of the method claim (even if very limited). Also any vibration applied externally to the breast would inherently be transmitted to a duct since the ducts are present in a majority of the breast. In other words, it would be impossible to vibrate the breast with out

Art Unit: 3764

vibrating a duct. Applying vibration to the duct would clearly increase the retrievable amount of cells collected from the breast duct.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brenden '403.

Similar to Endo above, Brenden discloses an ultrasound device that meets the limitation of the claims since Brenden discloses an ultrasonic vibration to the breast.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hung '228 in view of Endo.

Hung discloses in col. 11, lines 65- col. 12, lines 40 a method for increasing a retrievable cell amount, substantially as claimed. However, Hung discloses massaging the breast. Endo teaches applying vibration to the breast. It would have

Art Unit: 3764

been obvious to one having ordinary skill in the art at the time that the invention was made that vibration as taught by Endo could be substituted for massaging as disclosed by Hung because either movement could be used to move tissue in the breast duct to allow for movement of the tissue from the breast duct. Also, fast massaging of the breast would provide some vibration. Applying vibration to the breast duct would definitely increase the amount of cells that could be retrieved and collected from the breast duct.

Response to Arguments

Applicant's arguments filed June 20, 2006 have been fully considered but they are not persuasive. Applicant argues that the double patenting rejection should be withdrawn because Hung '026 teaches a method of ablating or damaging cells. However, the present invention teaches obtaining intact cells from a breast duct. However, the two methods recited in claims 1 and 3 of the present invention are similar in scope to claim 26 recited in U. S. Patent No. 6,391,026. Both methods disclose selecting a breast duct, inserting a device into the breast, to provide energy (vibration) to the duct, to ablate the cells (to collect the cells, removing the cells will cause some form of ablating because the cells will eventually die). Applicant argues that Endo doesn't disclose the method step of applying vibration to the breast duct sufficient to induce cell sloughing within the breast duct and then collecting the sloughed cells from the breast duct. However, Endo discloses inserting a vibrating device into a breast duct. Any vibration into a breast duct would inherently allow cell sloughing. The mere fact that vibration is applied to the duct would cause tissue to adhere to the device

Art Unit: 3764

inserted into the breast duct. Applicant argues that Brenden doesn't anticipate claim 1. However, as set forth above, any method step of inserting a vibration device into a breast duct would inherently cause cell slouching. Applicant argues that there is no motivation for combining Hung '228 with Endo. However, Hung was used to set forth the environment of a method of massaging a breast, which of course includes a breast duct. Endo was used as a modifier to substitute vibration for massaging. As set forth in the rejections, fast massage provides a form of vibration. Applicant argues that the prior art doesn't disclose collecting a retrievable cell amount through ductal lavage. However, collecting cells through the duct would inherently allow a certain amount of cells to be retrieved through ductal lavage.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Art Unit: 3764

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 571-272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gergory Huson can be reached on 571-272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Brown
August 25, 2006



MICHAEL A. BROWN
PRIMARY EXAMINER